

REMARKS

Applicant thanks the Examiner for the allowance of claim 9 and for the indication of allowable subject matter in claims 11, 18, and 19 in the above-identified application.

Applicant has cancelled claims 1-3, 6-8, 10, 12-17, and 20. After entry of the present amendment, claims 4-5, 9, 11, 18, and 19 are pending.

Applicant has rewritten claims 11 and 18 in independent form and to provide that the method for monitoring pain of a patient and the patient pain management system, respectively, are comprised of a patient communication device that includes a heat beam dolorimeter.

Applicant has amended claim 4 and claim 5 so that each claim includes the limitations of original claim 1 and original claim 3. Claim 4 has been further amended by deleting "administering pain medication using a patient controlled analgesia controller," "creating an output signal," and "signaling a patient."

Applicant has also amended the specification whereby the application claims priority under 35 U.S.C. §§ 119(e), 120, and 365(c). The application properly states that the above-identified application is a continuation-in-part of U.S. Application No. 09/453,770, filed December 2, 1999, now U.S. Patent, 6,248,079 (issued June 19, 2001).

Allowable Subject Matter

The Examiner indicated that claims 11, 18 and 19, if rewritten in independent form, would be allowable. The Applicant has amended claim 11 in independent form to include all limitations of original claim 1 from which original claim 11 depended. The Applicant has amended claim 18 in independent form to include all limitations of original claim 12 from which original claim 18 depended. Claim 19 now depends on amended claim 18.

Applicant respectfully requests allowance of claims 11, 18, and 19.

Objection to Specification

As suggested by the Examiner, Applicant has amended the first paragraph of the specification by properly claiming priority to Provisional Application No. 60/240,774, filed October 16, 2000, under 35 U.S.C. §119(e); claiming priority as a continuation-in-part of U.S. Application No. 09/453,770, filed December 2, 1999, now U.S. Patent, 6,248,079 (issued June 19, 2001), under 35 U.S.C. §120; and claims priority under 35 U.S.C. §365(c) from PCT/US00/41672, filed October 27, 2000.

Applicant respectfully requests that this objection be withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1-4, 6-8, 12-14, and 17 were rejected under 35 U.S.C. §102(b) as being anticipated by Iliff. Claims 1-4, 6, 7, 10, 12-17, and 20 were rejected under 35 U.S.C. §102(e) as being anticipated by Eberlein.

Applicant has cancelled claims 1-3, 6-8, 10, 12-17, and 20. Thus, both of these rejections have been rendered moot with regard to these claims.

Applicant has amended claim 4 to include all the limitations of original claim 1 and original claim 3 and has deleted “administering pain medication using a patient controlled analgesia controller,” “creating an output signal”, and “signaling a patient.” Applicant respectfully submit that amended claim 4 is not anticipated by either of these references.

First, Iliff does not teach a method that triggers an effector function to either gain attention of medical personnel or signal that a patient needs attention. Iliff discloses a method that “refers” patients to a physician (col 54, lines 3-4), but does *not* disclose a method that triggers a signal to gain the attention of medical personnel or triggers a signals that indicates a patient needs attention. Iliff relies on the patient contacting or calling the system (Col 53, line 51) and then only refers the patient to further assistance but does not signal the help for the patient (Col 54, line 3-4).

Second, Eberlein also does not teach a method that includes an effector function that gains the attention of medical personnel or signals that patient attention is required. While Eberlein does teach a method that includes a replay generator (Col 3, lines 7) and graphical displays (Col 3, lines 8-10 and Col 6, lines 2-3) as effector functions of the method, these functions do not trigger the attention of medical personnel or signal that patient attention is required. Furthermore, the graphical output is for later analysis rather than real time signaling because the pain information in Eberlein is "played back." (Col 6, line 2).

Applicant respectfully requests that both of these rejections be withdrawn with regard to claim 4.

Rejections Under 35 U.S.C. §103

Claims 1, 3-7, and 12-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson et al. in view of Levitas et al.

Applicant has cancelled claims 1-3, 6-8, 10, 12-17, and 20, thereby rendering this rejection moot with regard to claims 1, 3, 5-7, and 12-14.

Applicant has amended claim 4 to include all the limitations of original claim 1 and original claim 3 and has deleted "administering pain medication using a patient controlled analgesia controller," "creating an output signal" and "signaling a patient." Applicant has also amended claim 5 to include all the limitations of original claim 1 and original claim 3.

Claim 4. Examiner has rejected claim 4 as being unpatentable over Wilson et al. in view of Levitas et al. Applicant respectfully submits that amended claim 4 is not obvious from these combined references.

Wilson et al. does not teach any effector function that triggers medical personnel or signals that patient attention is required. Wilson et al. only discloses an apparatus with a historical data recording function for "later" analysis by health care personnel. (see col 15, lines 29-34). Under Wilson, since the information is

analyzed at a later time, the method and apparatus disclosed cannot trigger an effector function to notify when a patient currently needs attention.

Likewise, Levitas et al. also does not disclose an effector function that triggers medical personnel or signals that patient attention is required. Levitas et al. discloses a remote monitor/controller that has four basic functions and several modes that include monitoring and viewing (col 10, lines 27-46 & col 11, lines 21-37), but no mode to trigger attention of medical personnel or indicate that a patient needs attention.

Consequently, since Wilson et al. and Levitas et al. only disclose the historical analysis, the monitoring, and the viewing of data as possible effects of data collection, the combination of the two references does not create Applicant's claim 4.

Claim 5. Examiner has rejected claim 5 as being unpatentable over Wilson et al. in view of Levitas et al. Applicant respectfully submits that amended claim 5 is not obvious from these combined references.

Wilson et al. does not disclose an effector function of administering pain medication using a patient controlled analgesia controller **based** on the **processing** of subjective pain questionnaire results. Wilson et al. does not disclose or teach Applicant's amended claim 5 for three reasons. First, while Wilson et al. does disclose infusing analgesic "in response" to "periodic requests" by a patient, the administering of medication is infused whenever the patient merely presses a request key (Col 8, lines 54-58)—*not* after the processing or analysis of pain questionnaire results. Second, while Wilson et al. also discloses the questioning of a patient on the level of pain (cols 15-16, lines 65 & 1-2), it does *not* teach the processing of that questioning as a trigger for the administering of pain medication using a patient controlled analgesia controller. Third, Wilson et al. uses the answers to patient questions for "later" analysis to determine the "effectiveness of a particular infusion therapy" (col 15, lines 32-35)—such teachings disclose the use of patient questioning to provide historical analysis rather than processing patient questions to currently administer medication.

Similarly, Wilson et al. modified by Levitas et al. also does not provide a method with an effector function of administering additional pain medication using a patient controlled analgesia controller that is **based** on the **processing** of subjective pain questionnaire results. While Levitas et al. also discloses a pump with a pain controlled analgesic mode where the pump will infuse analgesic “in response” to “periodic requests” by a patient (col 6, lines 7-10), this references also does *not* teach a method to administer the medication *after processing* the subjective results of a patient pain questionnaire.

While Levitas et al. does teach the automatic analysis of patient medical condition data and the alteration of infusion therapy (Col 13, lines 31-34), such teaching does not generate the Applicant’s invention when combined with Wilson et al. Levitas et al. utilizes objective sensor data to alter a preprogrammed infusion therapy (e.g. sensors 40, 44, 48, 52, and 56 provide data on patient temperature, blood pressure, blood gas, pulse, and oxygen) (see col 13, lines 25-29 & fig 1). As a result, Levitas et al. together with Wilson et al. do not teach the administration of additional pain medication **after** delivering a subjective pain questionnaire to a patient, processing the pain questionnaire results, and triggering the patient controlled analgesic controller based on the subjective pain questionnaire results from the patient.

Because Wilson et al. discloses use of subjective pain questioning to only produce historical data and Levitas et al. discloses the use of objective data to alter programed therapy, combining Wilson et al. with Levitas et al. does not produce a method that administers additional pain medication during the course of therapy after processing subjective patient input through a questionnaire.

Applicant respectfully requests that these rejections be withdrawn.

CONCLUSION

Applicant respectfully requests that the Examiner allow pending claims 4, 5, 9, 11, 18, 19 and pass this Application to issue.

If the Examiner believes that a telephonic or personal interview would be helpful to terminate any issues which may remain in the prosecution of the Application, the Examiner is requested to telephone Applicant's attorney at the telephone number set forth herein below. The Commissioner is hereby authorized to charge any additional fees which may be required in the Application to Deposit Account No. 06-1135.

Respectfully submitted

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